



Virginia Department of Health

Influenza Vaccine Information Guide

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The purpose of this Influenza Vaccine Information Guide is to provide pertinent information regarding the Virginia Department of Health's (VDH) plan to provide flu vaccine for the 2005-2006 season. This guidance will offer a wealth of information including background on the flu and flu vaccine, vaccine recommendations, key messages and a timeline of the dissemination of press materials. This guide will highlight VDH procedures during this upcoming flu season and provide insight into VDH's efforts to protect the health and well-being of Virginia's citizens. The National Foundation for Infectious Diseases (<http://www.nfid.org/>) is the source for much of this background information.

Influenza Overview

Influenza caused an average of 36,000 deaths and more than 200,000 hospitalizations in the U.S. every year. Combined with pneumonia, influenza is the seventh leading cause of death in the nation. Influenza can lead to serious complications by aggravating existing medical conditions. It can also lead to infections of the brains, heart and other organs.

Influenza is a highly contagious virus that is spread easily from person to person, primarily when an infected individual coughs or sneezes. The virus can be transmitted even before influenza symptoms appear. The influenza virus causes "the flu," one of the most severe respiratory illnesses of the winter season.

Classically, influenza is characterized by the abrupt onset of high fever, muscle and joint pain, chills, a dry cough, headache, runny nose and a sore throat. Hospitalizations and deaths are often related to bacterial infections that complicate the primary infection with the influenza virus. Even among individuals who are not hospitalized, influenza can cause extreme fatigue that may last days or weeks.

Influenza Among Infants and Children

Rates of influenza are highest among children. Moreover, those younger than 24 months are hospitalized with influenza-related complications at rates similar to those 65 years and older. Additional findings show that when influenza viruses are circulating in the community, for every 100 children younger than 15 years of age, six to 15 outpatient visits are attributed to influenza. High-risk children, in particular, face increased risks from influenza infection. These children are five times more likely than healthy children of the same age to be hospitalized with influenza-related illnesses.

In addition to causing hospitalizations, influenza can be fatal in children. During the 2004-2005 influenza season, the Centers for Disease Control and Prevention (CDC) reported more than 32 influenza-related deaths among children younger than 18 years.

Despite the serious health threat, influenza immunization rates remain low for high-risk children. For example, more than 8 million infants and children with asthma should receive influenza vaccine each year. However, nearly 70 percent do not receive an annual immunization – this is the lowest vaccination rate for any recommended childhood vaccine in the U.S.

Missed opportunities for influenza immunization are common among children with chronic medical conditions. Children can be immunized at the same time they are given other routine vaccinations during the influenza season.

Influenza Infection in Health Care Workers

The CDC has long recommended annual influenza vaccination for all health care workers, yet only 36 percent of this population is immunized annually. Health care workers infected with influenza can transmit the highly contagious virus to patients in their care, who may be at high risk for influenza-related complications, leading to serious morbidity and mortality.

Research suggests unvaccinated health care workers can be a key cause of outbreaks in a variety of health care settings. Institutional influenza outbreaks can have serious implications – patients are at risk of contracting influenza; staff shortages can result or be exacerbated; admissions may be curtailed; and increased costs may be incurred. Published studies clearly demonstrate these outcomes.

CDC emphasizes that all health care workers should be vaccinated against influenza annually, and that facilities that employ health care workers be strongly encouraged to provide vaccine to workers by using approaches that maximize immunization rates.

Importance of Annual Immunization

Immunization provides the best protection against influenza. The optimal time to get vaccinated is in October and November as influenza season usually begins in December and it takes approximately two weeks after immunization to develop protective antibodies. The season usually peaks in January or February, and continues through March, so vaccination in December, January or beyond is still recommended for those who were not vaccinated earlier. The degree of vaccine effectiveness depends on several factors, including the age and health of the vaccine recipient and the match between circulating virus strains and those in the vaccine.

Vaccine Types

There are two types of influenza vaccine available: injectable trivalent inactivated influenza vaccine (TIV), and live attenuated influenza vaccine (LAIV).

TIV has been used safely and effectively for decades. The influenza virus used in the vaccine is “killed” and cannot cause influenza. The vaccine is approved for use in anyone 6 months of age and older, regardless of health status.

The nasal vaccine (LAIV) is an option for vaccination of non-pregnant healthy persons aged 5-49 years, including health care workers and other persons in close contact with groups at high risk and those wanting to avoid the spread of influenza.

Who Should Not Receive Influenza Vaccine

Individuals with egg allergies or those who have had a previous vaccine-associated allergic reaction should avoid immunization. Persons with acute febrile illnesses (high fever) should usually wait until their symptoms subside. However, vaccination can proceed during minor illnesses, with or without fever, particularly among children with mild upper respiratory tract infections and hay fever.

Certain groups should not receive LAIV, including persons younger than 5 years of age, those 50 years and older, children or adolescents taking aspirin, pregnant women and individuals with certain underlying medical conditions such as asthma and diabetes.

Adverse Effect of Influenza Vaccination

The most frequent adverse effect of the injectable influenza vaccine is soreness at the injection site for one or two days. Occasionally, some people experience a period of mild fever and fatigue for a day or two following immunization. The injectable vaccine is made from an inactivated, or dead, virus and cannot transmit infection.

Studies show that the side effects from the nasal influenza vaccine are generally mild and temporary. The most common is runny nose; others include various cold-like symptoms, such as headache, cough, sore throat, tiredness/weakness, irritability and muscle aches.

As with all vaccines, rarely an allergic reaction may occur in either the injectable or nasal influenza vaccines.

Vaccine Strain Selection

Each year, a new influenza vaccine is formulated to protect against predominant circulating influenza strains. The 2005-2006 influenza vaccine will include A/California/7/2004 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like and B/Shanghai/361/2002-like antigen. Because circulating strains mutate (change) constantly, it is not unusual that in some years the circulating influenza virus strains may not match exactly those contained in the vaccine. However, research has shown the vaccine is still protective against infection and reduces severity of influenza-associated complications.

Antiviral Drugs

Antiviral drugs for influenza are a complement to influenza vaccine for controlling and preventing influenza. Four licensed influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir and oseltamivir. Amantadine and rimantadine are chemically related antiviral drugs known as adamantanes with activity against influenza A viruses but not influenza B viruses. When administered within two days of the onset of illness to otherwise healthy adults, amantadine and rimantadine can reduce the duration of uncomplicated influenza A illness by approximately one day.

Zanamivir and oseltamivir are chemically related antiviral drugs known as neuraminidase inhibitors that have activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for treating uncomplicated influenza infections. Zanamivir is approved for treating persons 7 years or older, and oseltamivir is approved for treatment of persons 1 year and older. In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons 13 years or older.

Data is limited and inconclusive concerning the effectiveness of antiviral drugs among persons at high risk for influenza-related complications. In order to reduce the emergence of antiviral drug-resistant viruses, the CDC recommends discontinuing therapy as soon as clinically warranted. Use of antiviral drugs for prevention (prophylaxis) is not a substitute for vaccination, although in certain situations (i.e., outbreaks in institutions) they may be extremely helpful in preventing and controlling influenza.

Vaccination Recommendations

The Centers for Disease Control and Prevention (CDC) and VDH have instituted prioritization of inactivated influenza vaccine as a temporary measure to ensure that those persons who are at highest risk of complications from influenza have access to vaccine. Until **Oct. 24, 2005**, CDC recommends the following priority groups receive the inactivated influenza vaccine:

- People 65 years of age or older
- Children 6 to 23 months old
- Residents of long-term care facilities
- People with chronic cardiovascular or pulmonary disease, including asthma
- People with chronic metabolic diseases, kidney dysfunction, blood disorders or immune system problems
- Children and adolescents who are receiving long-term aspirin therapy
- Women who will be pregnant during the flu season.
- Health care professionals and any household contacts or care providers of children under 6 months of age. This helps prevent the spread of influenza to patients that may have existing health conditions and children who are too young to be vaccinated.

Beginning Oct. 24, 2005, all persons will be eligible for vaccination with the inactivated influenza vaccine, which can be administered to healthy and high-risk persons aged 6 months and older. Persons who should especially consider vaccination at this time include adults aged 50 and older and household contacts of any high-risk individuals.

These prioritized recommendations do not pertain to the live, attenuated influenza vaccine (LAIV), which can be administered at any time for vaccination of non-pregnant healthy persons from 5 to 49 years old, including most health care personnel and persons in close contact with high-risk groups. The LAIV is a spray form of the vaccine, often concentrated into a flu mist that is sprayed into the nostrils. In addition, antiviral medications are useful for early treatment of influenza, and as a supplement to influenza vaccination for disease prevention and control.

Key Messages

General Messages

- All indications at this point give VDH no reason to believe there will be a flu vaccine shortage this year. There are three manufacturers producing vaccine at this time. VDH ordered most of its vaccine from Sanofi Pasteur this year, which is expecting to produce 50 to 60 million doses for the U.S. market. VDH has also ordered a small amount of vaccine from MedImmune, the makers of the live attenuated flu mist vaccine.
- There is a potential for approximately 94 million doses of flu vaccine to be available this year if all manufacturers are able to deliver their planned number of doses.
- The CDC has issued guidelines for the distribution of flu vaccine and VDH will follow those recommendations to help meet the health needs of Virginia's citizens.
- VDH put in our order for 200,000 doses of vaccine in January 2005 to ensure that we were among the first in line when vaccine became available.

Increased Cost Messages

- VDH flu vaccine costs will be lower than the cost paid by the private sector. VDH purchases vaccine in large quantities using federal and state procurement contracts which limit the impact to VDH.
- There is a slight increase in the cost of vaccine this year. However, this increase did not play a role in the amount of vaccine doses that were ordered.
- The established fee for vaccine for the 2005-2006 season is \$28. That fee includes the cost of the vaccine, in addition to an administration fee for VDH to distribute the vaccine.
- The cost of a flu vaccine is minimal in comparison with other vaccines which can cost \$100 or more. The cost savings a vaccine provides in terms of doctor visits, hospitalizations, lost time at work and even the chance of death far outweighs the small increase in the price of a flu vaccine.
- The flu vaccine is not a large profit-making endeavor for the manufacturers. A modest increase in cost to help them cover their production expenses is a way to ensure that the manufacturers continue to make an ample supply of this vaccine.

2004 Flu Shot Shortage

- The 2004 shortage taught us that we need to do a better job of tracking the locations and availability of doses so that we can provide Virginians with good information about where and when they can get a flu shot.
- We also learned that we must work closely with pharmacists as well as health care providers to track available doses. This will help VDH to direct those in need of a vaccine to the nearest available supply.

General Info and Statistics

- VDH ordered 200,000 doses for the 2005-2006 flu season.
- Sanofi Pasteur, MedImmune and Chiron are VDH's vaccine suppliers, with the vast majority of our order coming from Sanofi Pasteur.
- In 2004, VDH distributed approximately 146,000 doses of the flu vaccine.
- In 2003, VDH distributed approximately 110,000 doses of the flu vaccine.